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Translation

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PS0304	FOR FURTHER ACT	ION '	See Form PCT/IPEA/416				
International application No.	International filing date	(day/month/year)	Priority date (day/month/year)				
PCT/JP2003/013254	16 October 2003	· · ·	16 October 2002 (16.10.2002)				
International Patent Classification (IPC) or national classification and IPC C12N 15/00, 15/09, 1/00, C12M 1/00 // A61K 48/00, A61P 35/00							
Applicant UNIVERSAL BIO RESEARCH CO., LTD.							
 This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36. 							
2. This REPORT consists of a total of	5 sheets, in	ncluding this cover s	heet.				
3. This report is also accompanied by A	ANNEXES, comprising:						
a. (sent to the applicant and	to the International Bure	au) a total of 7	sheets, as follows:				
sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).							
sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.							
b. (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s))							
4. This report contains indications rela	ting to the following item	s:					
Box No. I Basis of the re	eport						
Box No. II Priority							
Box No. III Non-establish	ment of opinion with rega	ard to novelty, inven	tive step and industrial applicability				
Box No. IV Lack of unity							
Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement							
Box No. VI Certain docur							
Box No. VII Certain defect							
Box No. VIII Certain observations on the international application							
Date of submission of the demand		Date of completion	of this report				
13 May 2004 (13.05.2004)		-	anuary 2005 (12.01.2005)				
Name and mailing address of the IPEA/JP		Authorized officer					
Facsimile No.		Telephone No.					



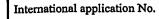
International application No.

PCT/JP2003/013254

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Box No.	I	Basis of the report						
1. With a otherw	regard vise in	i to the language, this report is based on the indicated under this item.	nternational application in the lang	guage in which it was filed, unless				
This report is based on translations from the original language into the following language, which is language of a translation furnished for the purpose of:								
ļ		international search (under Rules 12.3 and 2	3.1(b))					
		publication of the international application (under Rule 12.4)					
		international preliminary examination (under	r Rules 55.2 and/or 55.3)					
Ī								
furnis	hed to	d to the elements of the international apple the receiving Office in response to an invite annexed to this report):	ication, this report is based on ation under Article 14 are referre	(replacement sheets which have been ed to in this report as "originally filed"				
		international application as originally filed/fur	mished					
_		escription:						
	pages		4, 6-41	, as originally filed/furnished				
	pages pages		received by this Authority on received by this Authority on	01 November 2004 (01.11.2004)				
			on or any variable on					
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	pages pages		received by this Authority on	ether with any statement) under Article 19 01 November 2004 (01.11.2004)				
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	pages		received by this Authority on					
	a seo	uence listing and/or any related table(s) - see	Supplemental Box Relating to Se	quence Listing.				
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3.	The a	amendments have resulted in the cancellation	of:					
·	\Box	the description, pages						
	H	the claims, Nos.						
	H	the drawings, sheets/figs						
	H	the sequence listing (specify):						
	二	any table(s) related to sequence listing (spec						
		-, to sequence noting (spec						
4.	made	report has been established as if (some of) to, since they have been considered to go be 70.2(c)).	eyond the disclosure as filed, as	report and listed below had not been indicated in the Supplemental Box				
		the description, pages						
		the claims, Nos.						
		the drawings, sheets/figs						
		the sequence listing (specify):						
		any table(s) related to sequence listing (spec	:ify):					
* If item 4 applies, some or all of those sheets may be marked "superseded."								





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Box No. IV	Lack of unity of invention
1 Ir	response to the invitation to restrict or pay additional fees the applicant has:
	restricted the claims.
	paid additional fees.
	paid additional fees under protest.
	neither restricted nor paid additional fees.
2. Thi	is Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, to invite the applicant to restrict or pay additional fees.
3. This Autl	nority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
Con	nplied with.
⊠ not	complied with for the following reasons:
See	supplemental sheet
ļ	
	ently, this report has been established in respect of the following parts of the international application:
	all parts.
	the parts relating to claims Nos



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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: IV. 3.

The subject matter common to independent claims 1, 19, 27, 31 and 37 (invention group A) and independent claim 28 (invention group B) relates to a magnetic carrier.

However, the magnetic carrier is disclosed in JP 6-133784 A (Research Development Corporation of Japan), 17 May 1994 and hence, lacks novelty. There appears to be no other common subject matter that can be considered as a special technical feature.

Such being the case, it appears that there is no technical relationship between these two groups of inventions involving one of more of the same or corresponding special technical features and these two groups are not considered as being so linked as to form a single general inventive concept.



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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1.	Statement			
	Novelty (N)	Claims	1-27, 31-41	YES
		Claims	28-30	NO
	Inventive step (IS)	Claims	1-26, 31-41	YES
		Claims	27-30	NO
	Industrial applicability (IA)	Claims	1-41	YES
		Claims	. 	NO NO

2. Citations and explanations

Document 1: JP 7-241192 A (TDK Corp.), 19 September 1995

Document 2: JP 6-133784 A (Research Development

Corporation of Japan), 17 May 1994

Document 3: F. Toneguzzo, et al., "Electric field-

mediated gene transfer: characterization of

DNA transfer and patterns of integration in

lymphoid cells." Nucleic Acid Research,

1988, Vol. 16, No. 12, pages 5515-5532

Document 4: WO 94/09145 A1 (Cangene Corporation), 28

April 1994

Document 5: EP 866123 A1 (Eppendorf-Netheler-Hinz GmbH),

23 September 1998

Claims 1-26 and 31-41

The inventions set forth in claims 1-26 and 31-41 are novel and involve an inventive step in relation to documents 1-5 cited in the international search report.

Document 1 discloses an apparatus for introducing biological material having a specific structure and a method for introducing biological material for introducing desired genes into target cells through the application of a magnetic field. Document 2 discloses specific magnetic particles for the introduction of biological material and a cell separation process using said magnetic particles.



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Documents 3-5 disclose a process for perforating cells.

However, none of the above-listed documents discloses or suggests an apparatus for introducing biological material and a method for introducing biological material for introducing desired DNA into target cells through the application of a magnetic field, wherein magnetic fields are applied from at least two directions to the container unit with said container unit situated between the fields. Moreover, this feature would not be obvious to a person skilled in the art.

Claim 27

The invention set forth in claim 27 does not involve an inventive step in the light of documents 1 and 2 cited in the international search report.

The invention set forth in independent claim 27 does not specify the feature wherein magnetic fields are applied from at least two directions to the container unit with said container unit situated between the fields.

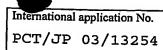
Consequently, it would be easy for a person skilled in the art to conceive of configuring the invention pertaining to the introduction of biological material presented in document 1, so that the form of the particles is modified into a known form, such as that disclosed in document 2, in order to improve the introduction rate of the particles.

Claims 28-30

The invention set forth in claims 28-30 lacks novelty and does not involve an inventive step in the light of document 2 cited in the international search report.

Document 2 discloses magnetic particles used in the introduction of biological material into cells and indicates that it is preferable for the shape of said magnetic particles to be non-spherical and to have corners





and for them to be a needle shape preferable with a rodshaped cross section. Needle-shaped magnetic particles are usually considered to be magnetized in a longitudinal direction and to be easily magnetizable.